QIBA CT Angiography Biomarker Committee (BC) Call

11 February, 2019 at 11 AM CT Call Summary

On Call

Andrew Buckler, MS (Co-Chair)

Alexander Guimaraes, MD, PhD

Taylor Richards, PhD

Joe Koudelik

Luca Saba, MD (Co-Chair)

Edward Jackson, PhD

Marly van Assen, MSc

Susan Stanfa

Kevin DeMarco, MD

Márton Kolossváry, MD

Edwin van Beek, MD, PhD

Svetlana Egorova, MD, PhD

Nancy Obuchowski, PhD

Moderator: Andrew Buckler, MS

Remaining Sections for Profile Discussed

- Consensus reached for the dose table to be moved to Section 4.2: Assessment Procedure: Voxel Noise
- All Profile sections besides Claims have been written; claims are made based upon specifics associated with the biomarker
 - Statistical performance metrics
 - Methodology used to select appropriate metrics and how to assess them, e.g. challenge, phantom study
- While a broad meta-analysis has not been conducted, a systematic review of some literature has been done
 and incorporated into literature analysis section, Appendix E: CT Angiography Signal Applicability and
 Published Performance
- Look into what constitutes good performance
 - Literature used incorporated into literature analysis section
 - Need claims that multiple vendors and actors can reasonably aspire to meet or exceed requirements; the idea is to encourage innovation
 - Balance needed between high-performance (to elevate the field), and "reasonable" performance (to avoid user push-back)
 - Claim performance table contains specifications based on a systematic review of limited literature; a broad meta-analysis was suggested, but this would require volunteers
 - Clinical claim may discourage broader use of Profile for users with less-than-ideal performance; i.e., is the bar being set too high?
 - Dr. Obuchowski supports the idea of an algorithm challenge to see where the field is today and get a better perspective regarding the performance distribution suggestion made to do this prior to pursuing public comment, but this will likely hold off the Profile development for a year or more, based on prior QIBA challenges, so consensus that this may be pursued in parallel with, rather than before, public comment.
 - Discussion re: sample size and its impact on confidence interval
 - Claim can be used for clinical trial or clinical guidelines that impact clinical care
 - Agreement that a large sample size would be ideal, but there are limitations regarding types of study (e.g., cost, time, etc.)
 - Dr. Obuchowski & Mr. Buckler to review statistical performance metrics in Section 3, offline
 - The lack of data for quantitative imaging biomarkers was identified as a problem
 - Need to collect data to establish clinical utility

- Goal is to validate and move field forward: the Profile would provide a guideline to developing future studies that could provide "good data"
- Two separate performance tables could be used if coronary vs. carotid had
 differences in bias and variability, but the data shows this to not be needed. What is
 the case is that the level of performance, stated in original units, reflects that the
 smaller the vessel the more significant the performance level. This doesn't require
 multiple tables but is noted for understanding the significance of the numbers.
 Discussion to be continued during next meeting
- Suggestion to move forward with three parallel (not sequential) activities (after the 2/25 t-con)
 - o 1. Move forward with public comment
 - o 2. Start feasibility testing
 - o 3. Arrange public challenge of image analysis software

Next call: Monday, February 25th at 11 am CT (the same topics will be covered to encourage input/feedback)

QIBA Wiki CT Angiography BC page: http://qibawiki.rsna.org/index.php/CT Angiography Biomarker Ctte